Validation & Monitoring Solutions

Application Note • Medical
June 2019

Bowie Dick Testing – Routine Control of Autoclaves

Background

Ensuring that surgical and procedural hospital equipment is completely clean and sterile is of utmost importance to protect patients against infections and contagious diseases. In order to do that, Central Sterilization Service Departments (CSSD's) wash equipment in washing disinfectors before sterilizing them in large steam sterilizers, also known as autoclaves. As patient safety is on the line, these autoclaves are tested daily to ensure that they operate and sterilize as intended.

The majority of hospitals use large autoclaves (above 60L) and are therefore required to carry out daily steam penetration tests as a routine control according to the standards EN 285 and ISO 17665. The most commonly used steam penetration test is a so-called Bowie Dick Test, which was originally developed by Dr. J. Bowie and J. Dick in 1963 to monitor the air removal efficiency in steam sterilizers. Their test consisted of a large number of folded towels containing a sheet of paper equipped with chemical indicator tape. If the heated steam within the autoclave successfully passed through the towels and caused all of the tape to react, the test result would be considered a pass. The purpose of the Bowie Dick test is to check whether the air-removal system within the autoclave successfully removed any excess air and other non-condensable gasses (NCG's) – thereby ensuring that saturated steam reaches- and properly sterilizes all parts of the equipment.

The industry has come a long way since applying a large bundle of towels in their autoclaves, usually settling for traditional chemical indicators or modern electronic tests instead. However, the original Bowie Dick test remains the reference method for compliance testing of alternative Bowie Dick test methods.

Chemical Indicators

As mentioned, chemical indicators have been used to determine if the autoclave has reached saturated steam. Chemical indicators consist of layers of paper and a special test sheet that changes color if the steam successfully reaches it. The change in color is then subjectively determined to either mean pass or fail. This raises an issue, as a slight change in color can prove detrimental if read incorrectly. In addition to this, the accuracy of these indicators has recently come into question, as several studies have shown them to provide false positives – thereby jeopardizing patient safety.

Electronic Bowie Dick Tests

Due to the aforementioned issues and storage difficulties associated with chemical indicators; electronic alternatives have been available on the market for some time now, performing daily routine- and batch control of autoclaves to test their capabilities. Electronic Bowie Dick tests objectively measure and evaluate critical physical parameters of the sterilization process, providing more accurate results and eliminating any guess work.

Learn more about SteriSense® or other solutions to fit your needs here:

ellab.com • contact@ellab.com

Validation & Monitoring Solutions

Application Note • Medical
June 2019

Batch Control and Parametric Release

Whereas the daily routine control of autoclaves is performed to “release” autoclaves in the morning, batch control is used to prove that loads are sterilized according to the Safety Assurance Level (SAL). Historically, biological indicators have been the go-to method for performing batch control of steam sterilizers. These indicators consist of an ampule that contains a defined number of microbiological spores in suspension, which are counted post sterilization to detect the survival rate – a rather time-consuming process. However, electronic test units have now also been introduced for performing quick and efficient batch controls. These devices are introduced alongside the batch and read post sterilization, providing immediate results and allowing for parametric release.

Parametric release is a principle that requires measured data of critical physical parameters by an independent electronic device. Electronic devices and the parametric release method comes with some distinct advantages when compared to traditional indicators/methods:

- Data is presented with a clear pass/fail result, removing any subjective assessment and the risk of misreading
- The result is presented immediately after the test, allowing the batch/load to be released right away. Whereas biological indicators require incubation and resource dependent assessments before a batch/load can be released for use
- Electronic devices are economically efficient with high test volumes, data is easy to store, retrieve and compare as it is all conveniently located in a database for safe operation
- Electronic solutions also result in less waste products, thereby providing a more environmentally friendly process

Choosing the Ultimate Electronic Bowie Dick Test Device

Ellab has recently launched the ISO 11140-4 compliant SteriSense® system, a new and innovative product for electronic Bowie Dick testing and batch control, which is unrivaled in terms of user-friendliness, size, accuracy, performance and reliability.

The extremely compact device ensures patient safety by revealing potentially faulty sterilizers that may otherwise have passed less reliable methods – and with annual calibrations, the SteriSense sensors remain highly accurate all year round.

SteriSense is equipped with a game changing interchangeable Process Challenge Device (PCD), which is what really sets it aside from other electronic Bowie Dick testing devices. The interchangeability means that operators no longer have to wait for equipment to cool or purchase additional backup devices for subsequent runs – instead, they can simply unscrew the PCD and replace it with a spare before running another cycle.

The SteriSense software is extremely user-friendly and requires next to no training. With just a single click, the measuring unit is started and ready to be placed in the process. Once the program is complete, the device is read, immediately evaluating the data and providing a clear Passed or Failed result. If more detailed information is required, reports can be generated, evaluated and saved, ensuring full electronic documentation of the process.

Learn more about SteriSense® or other solutions to fit your needs here:

ellab.com • contact@ellab.com